FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORP., et al.,	x	Hon. Stanley R. Chesler, U.S.D.J.
plaintiffs,	x	
	x	Civil Action No. 04-4030
v.	x	
	x	**OPINION**
TEVA PHARMS. USA, INC,	x	**FILED: February 6, 2006**
defendant.	x	

CHESLER, District Judge

APPEARANCES

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I. INTRODUCTION

In this Hatch-Waxman Act patent infringement case, defendant Teva Pharmaceuticals USA, Inc. ("Teva") moves pursuant to Federal Rule of Civil Procedure 12(c) for judgement on the pleadings with respect to plaintiffs Celgene Corporation, Novartis Pharmaceuticals Corporation, and Novartis Pharma AG's (collectively "plaintiffs") allegation of willful infringement. For the reasons that follow, Teva's motion is **GRANTED.**

II. BACKGROUND

A. The Hatch-Waxman Act

The Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-99, ("FDCA") provides that a company seeking to market a new brand-name drug must submit a New Drug Application ("NDA"). See id. § 355(b)(1). NDAs are generally lengthy applications that include information about the drug such as evidence of its safety and effectiveness, and information about the patents that cover or might cover it. Id. Before Congress passed the Hatch-Waxman Act, a generic drug manufacturer's use of a patented drug was considered patent infringement. This was so even if such use of the patented drug was limited to testing for Food and Drug Administration ("FDA") approval to market its generic equivalent upon expiration of the relevant patents. Accordingly, companies seeking to market generic drugs upon the expiration of patents that covered them were impeded by the cost of filing lengthy NDAs, which they could begin to prepare only upon the expiration of the brand-name drug company's patents. The time it took generic companies to prepare the NDA and obtain FDA approval caused a de facto extension of the patent covering the brand-name drug.

Recognizing the benefit in reducing delays in FDA approval of generic drugs, and as a

means to eliminate the de facto extension of the end of a patent term, Congress enacted the Hatch-Waxman Act amendments to the FDCA. The Hatch-Waxman Act conferred two main benefits upon generic drug manufacturers. First, it allowed them to avoid the costly NDA process by filing an Abbreviated New Drug Application ("ANDA") which, in effect, "'piggyback[ed]' on the safety-and-effectiveness information that the brand-name manufacturers submitted in their NDAs." Purepac Pharm. Co. v. Thompson, 354 F.3d 877, 879 (D.C. Cir. 2004) (citing 21 U.S.C. § 355(j)(2)(A) and 21 C.F.R. § 314.94(a)(3)). Thus, among other things, an ANDA must show the proposed generic drug is chemically bioequivalent to a drug that was previously approved by the FDA. 21 U.S.C. § 355(j)(4)(F).

ANDAs must also address patents that cover the drug for which approval is sought. 21 U.S.C. § 355(j)(2)(A)(vii) allows an applicant to satisfy this requirement by including in its ANDA one of several types of "certifications" explaining why the FDA should approve the application despite the patent's claim on the drug. The certification at issue here is a "Paragraph IV Certification" (named for its statutory sub-paragraph), which states "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug." Id. 355(j)(2)(A)(vii)(IV). Applicants use Paragraph IV Certifications to essentially challenge the validity of the brand-name drug manufacturers' patents. An applicant that includes a Paragraph IV Certification in its ANDA must inform both the patent holder and the company that submitted the NDA on which the ANDA "piggybacks." Id. § 355(j)(2)(B)(i). Once notice is served, the FDA must wait forty-five days before approving the ANDA, giving the patent holder the opportunity to file suit. Id. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(f)(2). When a Paragraph IV Certification is filed, therefore, the brand-name drug manufacturer is forced to litigate to protect

its rights.

If the patent holder sues, the FDA cannot approve the ANDA until the earlier of (A) thirty months from the notice date, (B) the applicant wins the suit, or (C) a date to which the court hearing the suit shortens the thirty month period. 21 U.S.C. § 355(j)(5)(B)(iii). If successful in its challenge, the FDA may approve the ANDA and allow the applicant to market the generic version of the brand-name drug before the expiration of patents covering it. The Act rewards the first generic drug applicant that successfully challenges the patent of an approved drug with a 180-day period in which it may exclusively market the generic version. Id. § 355(j)(5)(B)(iv).

The second benefit of the Hatch-Waxman Act to generic drug manufacturers was a limitation on the potential patent infringement liability to companies that seek FDA approval to market a generic version of the brand-name drug. See 35 U.S.C. § 271(e)(1). While the Act immunizes generic drug manufacturers from patent infringement liability for preparing an ANDA, Section 271(e)(2)(A) provides a jurisdictional basis for an infringement action against the applicant where it seeks approval to market a patented product before the expiration of the patent. The purpose of this provision is "to define a new (and somewhat artificial) act of infringement for a very limited and technical purpose that relates only to certain drug applications." Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676 (1990). Thus, if the patent holder sues the applicant within 45 days from the notice, its remedies are limited to the following:

> (A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

> (B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product, and
>
> (C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product.
>
> The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

35 U.S.C. § 271(e)(4).

Section 285, which applies generally to patent infringement cases, provides "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285. In determining whether or not a case is "exceptional" under Section 285, courts "look at the totality of the circumstances." Yamanouchi Pharm. Co. Ltd. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1347 (Fed. Cir. 2000). In typical patent infringement cases, the United States Court of Appeals for the Federal Circuit has found "exceptional cases" in cases of "inequitable conduct before the PTO, litigation misconduct such as vexatious or unjustified litigation or frivolous filings, and willful infringement." Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1350 (Fed. Cir. 2004) (citing Hoffman-La Roche Inc. v. Invamed Inc., 213 F.3d 1359, 1365 (Fed. Cir. 2000); Rosemount, Inc. v. Beckman Instruments, Inc., 727 F.2d 1540, 1548 (Fed. Cir. 1984)). The Federal Circuit has not held that attorney's fees under Section 285 are recoverable based on a finding of willful infringement in a Hatch-Waxman Act case.

It is against this backdrop that the Court considers the allegations of the plaintiffs'

complaint and defendant's 12(c) motion.

B. Plaintiffs' Allegations

This case presents patent infringement claims under the Hatch-Waxman Act by the plaintiffs, who hold rights in United States Patent No. 5,908,850 ("the '850 patent"), against Teva, a generic drug manufacturer. Plaintiffs market FOCALIN™, a drug that practices the '850 patent. They allege that Teva infringed the '850 patent by filing an ANDA and an amended ANDA with the FDA, which seek approval to market a generic version of FOCALIN™. (Complt. at ¶ 12-14.) The ANDA contains a Paragraph IV Certification stating that Teva believes the '850 patent to be invalid. (Id. at ¶ 15.) Plaintiffs claim the products for which Teva seeks approval are bioequivalent to the patented FOCALIN™ products, have the same ingredients as the patented FOCALIN™ products, have the same route of administration, dosage form and strength as the patented FOCALIN™ products, and have the same, or substantially the same, proposed labeling, and the same indication and usage as the patented FOCALIN™ products. (Id. at ¶ 19.) Plaintiffs allege "Teva had notice of the '850 patent beginning prior to undertaking its act of infringement. Teva's infringement has been, and continues to be, willful and deliberate." (Id. at ¶ 22.) They seek damages, including "[a]ttorney's fees in this action pursuant to 35 U.S.C. § 285." (Id., Prayer For Relief at subpara. (G), p. 6.)

C. The Instant Motion

Teva's motion for judgment on the pleadings is directed at paragraph 22 of the Complaint, which alleges "Teva had notice of the '850 patent beginning prior to undertaking its act of infringement. Teva's infringement has been, and continues to be, willful and deliberate." Teva argues this allegation should be stricken because (1) a declaration of willful infringement is

not within the limited remedies provided for by 35 U.S.C. § 271(e)(4) (Defendant's Moving Brief at 5-6); (2) plaintiffs' allegations cannot support a finding of willful infringement as a matter of law under the Glaxo and Yamanouchi cases (id. at 6-9); and (3) willful infringement is part of a damages calculation under 35 U.S.C. § 284, not a remedy in Hatch-Waxman litigation (id. at 9-11). For these reasons, Teva asks that the Court strike plaintiffs' allegation of willful infringement.

In opposition, plaintiffs argue, first, that Magistrate Judge Hughes previously denied Teva's Glaxo motion and allowed discovery on the issue of willfulness. (Opposition Brief at 5-6.) Second, they argue that Glaxo does not bar a finding of willful infringement to support an award of attorneys fees in a Hatch-Waxman Act case. (Id. at 7-9.) Third, they argue the factual record reveals extreme willfulness on Teva's part. (Id. at 9-10.) Namely, plaintiffs argue Teva obtained the idea for the accused product in violation of a confidential disclosure agreement, its Paragraph IV Certification is baseless, and it had not come forward with any better prior art. (Id. at 9-10.) For these reasons, plaintiffs argue they should be permitted to develop the record on the willfulness issue. (Id. at 10.)

In its reply, Teva argues plaintiffs' argument that they should be permitted to develop the record is misplaced because this is a Rule 12(c) motion, which examines the pleadings, not the proof. (Reply at 1.) Moreover, they argue Judge Hughes' ruling allowing discovery on willfulness, which has been stayed, was not the equivalent of a ruling on the 12(c) motion. (Id. at 3.) Teva further argues that plaintiffs do not allege violations of the confidential disclosure agreement and cannot use this as a basis for a finding of willfulness. (Id. at 4.) Teva notes that this Court has held in the case of Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc., 04-1689

(D.N.J. 2005), that there can be no willful infringement based solely on an allegedly baseless Paragraph IV Certification. (Id. at 4.) Teva then recites the basis for its Paragraph IV Certification to refute plaintiffs' contention that it is baseless. (Id. at 4-14.)

III. DISCUSSION

A. Judgment on the Pleadings Standard

The standard for deciding a motion for judgment on the pleadings under Federal Rule of Civil Procedure 12(c) is identical to that under Rule 12(b)(6). All allegations in the Complaint must be taken as true and viewed in the light most favorable to the plaintiff. Gomez v. Toledo, 446 U.S. 635, 636 n.3 (1980); Robb v. Philadelphia, 733 F.2d 274, 277 (3d Cir. 1984). If, after viewing the allegations in the light most favorable to the plaintiff, it appears beyond doubt that no relief could be granted under any set of facts which could be proved consistent with the allegations, a court shall dismiss for failure to state a claim. Hishon v. King & Spalding, 467 U.S. 69, 73 (1984); Zynn v. O'Donnell, 688 F.2d 940, 941 (3d Cir. 1982). The narrow issue before the Court, therefore, is whether or not defendant could be found to have engaged in an act of "willful infringement" in this Hatch-Waxman Act case.

B. Willful Infringement

The Court of Appeals for the Federal Circuit has held that the prevailing plaintiff in a Hatch Waxman case may recover attorney's fees under Section 285 in "exceptional cases." In Yamanouchi Pharmaceuticals Company v. Danbury Pharmacal, Inc., the owners of a patent that covered an anti-ulcer drug brought a Hatch-Waxman Act suit against a generic drug manufacturer that filed an ANDA and Paragraph IV Certification, which argued their patent was invalid for obviousness. 21 F. Supp. 2d 366 (S.D.N.Y. 1998). After a bench trial, the United

States District Court for the Southern District of New York held the patent was valid, id. at 374-75, and awarded plaintiffs attorney's fees, id. at 378. In awarding attorney's fees, the court found that the generic drug company's filing of a baseless Paragraph IV Certification constituted willful patent infringement. Id. at 377 n.18. Defendants appealed to the Court of Appeals for Federal Circuit.

The appellate court did not agree with the district court that the generic company had engaged in willful infringement. 231 F.3d at 1347 (stating that the trial court "need not have elevated the ANDA certification into a finding of willful infringement"). Rather, it held that the generic drug company's numerous baseless filings in support of meritless arguments presented "exceptional circumstances" under Section 285. Id. at 1347-48. The Yamanouchi court, therefore, did not award legal fees for willful infringement.

The Federal Circuit clarified Yamanouchi with its holding in Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339 (Fed. Cir. 2004). In Glaxo, defendant filed an ANDA for permission to market a generic version of an antibiotic drug covered by the plaintiffs' patents. Reversing the district court, the Federal Circuit held that "the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement for purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4)." 376 F.3d at 1350-51. The court reasoned as follows:

> The Supreme Court has emphasized that 35 U.S.C. § 271(e)(2) and 35 U.S.C. § 271(e)(4) create an "artificial" act of infringement only for a "very limited and technical purpose that relates only to certain drug applications." . . . . This purpose, as the Supreme Court explains, is to permit patent holders to bring suit against generic companies despite the fact that the generic companies have not yet infringed the patents at issue . . . . In evaluating 35 U.S.C. §

> 271(e)(2), we have in our past decisions considered this provision to be primarily a jurisdictional-conferring statute that establishes a case or controversy in a declaratory judgment action.

Id. at 1351 (citations omitted). Thus, the Glaxo Court held that the district court "erred in hanging a finding of willfulness on such a special purpose peg." Id.

District courts that have addressed the issue have disagreed as to whether or not there can be a finding of willful infringement based upon the filing of an ANDA and Paragraph IV Certification. Compare Novartis Pharms. Corp. v. Teva Pharms. USA, Inc., Civ. A. No. 05-1887 (D.N.J. Dec. 30, 2005) (holding it is possible that Novartis may be able to show activity in addition to the ANDA filing to support its claim of willfulness); Wyeth v. Teva Pharms. USA, Inc., Civ. A. No. 03-1293 (D.N.J. Aug. 5, 2004) (finding there could be activity to support willfulness on top of the filing of an ANDA and permitting discovery on the issue); Eisai Co., Ltd., v. Dr. Reddy's Labs., Ltd., Civ. A. No. 03-9053 (S.D.N.Y. Oct. 12, 2004) (denying motion to strike allegations of willfulness and holding the Federal Circuit did not "say there can be no willful infringement in an ANDA case"); AstraZeneca AB. v. Andrx Pharm., LLC, Civ. A. No. 04-80 (D. Del. Aug. 11, 2004) (holding that a Paragraph IV Certification could be considered in determining willfulness) with Aventis Pharma Deutschland GMBH v. Lupin Ltd., -- F. Supp. 2d --, 2006 WL 141670, at *7 (E.D. Va. Jan. 18, 2006) (holding "even a baseless ANDA filing could not constitute an act of willful infringement, though [it] could constitute an exceptional circumstance."); Aventis Pharma Deutschland GMBH v. Cobalt Pharms., Inc., 355 F. Supp. 2d 586, 593 (D. Mass. 2005) (holding allegations that defendant filed a baselss ANDA and Paragraph IV Certification are "artificial act[s] of infringement" and "cannot be considered willful [infringement]"). For the reasons that follow, this Court agrees with those district courts

that have held there can be no "willful infringement" where, in cases such as this, the allegedly infringing conduct is limited to the highly technical act of infringement sufficient to confer jurisdiction under the Hatch-Waxman Act.

C. Analysis

The Court finds that plaintiff could not recover under the theory that Teva willfully infringed the '805 patent. The Glaxo case makes clear that the Hatch-Waxman Act exists for the very limited purpose of creating a technical infringement so that United States district courts can decide whether or not a proposed generic drug, if manufactured, would infringe. Its purpose is to permit the matter to be decided before the drug goes to market and an actual, rather than artificial, act of infringement occurs. See Glaxo, 376 F.3d at 1351; Lupin, 2006 WL 141670, at *7 ("[T]he fact that the appellate court in Glaxo emphasizes that the purpose of the ANDA process is to create an 'artificial' act of infringement for jurisdictional purposes strongly supports this Court's conclusion that even a baseless ANDA filing may never constitute willful infringement."). Thus, the artificial and highly technical nature of Teva's "infringement" does not rise to the level of a literal act of patent infringement that could give rise to a finding of "willful infringement," as the phrase has been applied under Section 285. While plaintiffs argue Teva's breach of the confidential disclosure agreement supports a finding of willfulness, they have not pled such conduct. Moreover, such conduct perhaps could state a claim for breach of contract but it does not further the plaintiffs' cause with regard to their claim of willful patent infringement. Accordingly, this Court will grant Teva's motion.

This holding does not prohibit plaintiffs from applying for attorney's fees under the "exceptional cases" provision of Section 285 if they prevail. Willful infringement, however,

cannot be among the exceptional circumstances unless and until actual infringement occurs. See, e.g., Glaxo, 376 F.3d at 1351 (stating that the purpose of the ANDA filing "is to permit patent holders to bring suit against generic companies despite the facts that the generic companies have not yet infringed the patents at issue."); Cobalt, 355 F. Supp. 2d at 593 ("[T]he prevailing party may seek to prove that this is an exceptional case, like Yamanouchi, involving serious and persistent litigation misconduct."). The Court simply holds that plaintiffs cannot prove willful infringement based upon Teva's alleged conduct to date.

IV. CONCLUSION

For all of the foregoing reasons, plaintiff's motion is **GRANTED** and paragraph 22 of the Complaint is stricken. The Court will issue an appropriate Order.

/s/Stanley R. Chesler
United States District Judge